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October 21, 2024

Via ECF
Honorable Thomas I. Vanaskie, Special Master
Stevens & Lee, P.C.
1500 Market Street, East Tower, 18th Floor
Philadelphia, Pennsylvania 19103

Re: *In re Valsartan, Losartan, and Irbesartan Products Liability Litigation*, No. 1:19-md-02875 (D.N.J.)

Dear Judge Vanaskie:

Please accept this agenda letter on behalf of Plaintiffs in advance of the October 22, 2024 case management conference.

1. Identification of Bellwether Cases.

Twenty-eight cases were selected as personal injury Bellwether cases. Plaintiffs have attached a chart at the bottom of this letter which lists the name of each plaintiff, which side selected the case, the cancer diagnosis, and which defendants are at issue in each case, based on the available information. It is possible that some of the information set forth will need to be corrected through a meet and

confer between the parties.

2. The Number and Order of Bellwether Trials.

This MDL has been pending for over five years, and the personal injury plaintiffs either have cancer or have since passed away. Time is of the essence for these plaintiffs, who eagerly await their day in court.

The first bellwether trials should be drawn from the bellwether pool. The Parties previously completed additional written discovery, depositions of the plaintiffs, depositions of prescribing and treating physicians.

Plaintiffs submit that it would be most efficient and helpful to progressing the litigation to focus on the defendants who were the subject of the recently postponed economic loss trial, and in particular ZHP - the manufacturer of the API used in the largest share of cases. This will allow the Parties and the Court to use the extensive work performed in connection with the postponed trial in turning to the personal injury track.

In addition, Plaintiffs submit that the cases to be selected should include the two most numerous cancers across the litigation, liver cancer and colorectal cancer. In addition to providing helpful information across the litigation in terms of value and resolution, the liver cancer cases have the added benefit of directly applying the Gomm, Pottegard, and Mansouri studies finding an increased risk of liver cancer

arising from the use of the contaminated valsartan pills.

Plaintiffs believe that the litigation should focus on multi-plaintiff trials, which is a common practice in MDL litigation to increase the efficiencies each time a jury is selected. However, in order to avoid a dispute over the first trial (Defendants are opposed to multi-plaintiff trials)(, and in the interest of streamlining the process to get to the first trial sooner, Plaintiffs submit that the first bellwether trial should be a single-plaintiff liver cancer case involving only the ZHP API and other downstream defendants (if any). Then, the second bellwether trial should be a multi-plaintiff colorectal cancer case against only the ZHP API and other downstream defendants. The work-up of other cases involving other cancer types and defendants can be addressed once the process to move forward to the first trial has gotten underway.

A. CANCER TYPE

For bodily injury cancer cases, the general causation analysis focus on whether the NDMA/NDEA in the VCD's was capable of causing or substantially contributing to a plaintiff's cancer. According to data from the 1083 completed version 1 plaintiff facts sheets, approximately 35% of the plaintiffs in this litigation have been diagnosed with colorectal cancer and approximately 18% of the plaintiffs in this litigation have been diagnosed with liver cancer. These are the two most

common cancer types that plaintiffs have been diagnosed with in this litigation. As touched on above, it was the Defendants who raised the Mansouri study with the Court. That study showed a statistically significant increased risk of liver cancer due to valsartan usage and corroborated the findings from the Gomm study that also showed a statistically significant increased risk of liver cancer due to valsartan usage. The first bellwether trial should be a single-plaintiff liver cancer case against only the ZHP API and other downstream defendants.

For the second trial, there are several colorectal cancer cases in the bellwether pool, so a multi-plaintiff colorectal cancer case against only the ZHP API and other downstream defendants can be scheduled for the second trial, allowing the parties the time needed to prepare a multi-plaintiff trial. By focusing the first two bellwether trials on liver and colorectal cancer, the first two trials would be representative of the most numerous overall cancer types in this litigation.

B. ZHP API DEFENDANTS

At this time, the depositions, briefing, Daubert rulings, and extensive legal rulings (a number of which will be applicable in the personal injury context, or at least instructive) related to the ZHP API defendants (ZHP, Teva, and Torrent) have been largely completed. In addition, the deposition designations for ZHP, Teva, and Torrent have mostly been completed, needing only to be modified to add general

causation testimony, testimony regarding consumers as opposed to TPPs, and remove testimony only applicable to economic loss (e.g. IQVIA). These first two trials will be far more efficient to work up and take to trial, without the Mylan, Aurobindo, and Hetero API defendants. A separate track of developing the liability experts against Mylan and Aurobindo, as well as the deposition designations, should proceed concurrently with the first two bellwether trials. The Hetero defendants have settled the valsartan bodily injury claims and the administration of the settlement will be occurring in the next few months. Therefore, the first two bellwether cases should only include cases from the bellwether pool where the plaintiff only used the ZHP API valsartan (and not the Mylan, Aurobindo, or Hetero API valsartan).

Plaintiffs understand that Defendants intend to request random selection or selection of cases by both sides. Plaintiffs believe that prioritization of the liver and colorectal cancer cases, and focus on cases involving the ZHP API would be most efficient and logical.

3. *Lexecon* Waivers.

To the extent leadership represents the plaintiff, we can represent that we will recommend that our clients waive *Lexecon* and allow the cases to be tried here in the MDL Court (where necessary, taking into account the presence of ZHP, Teva, and Torrent in New Jersey). To the extent a plaintiff is not represented by leadership, the

PEC will reach out to that counsel and attempt to obtain agreement on a case-by-case basis, as needed.

4. **The scope of any remaining fact discovery for the bellwether cases selected for trial.**

Plaintiffs do not believe there is a need for further written discovery. In certain cases, there are additional fact depositions that may need to be taken, though a large number of depositions have already occurred.

Plaintiffs, and potentially Defendants, will seek leave to conduct de bene esse depositions of certain experts in order to ensure that their testimony is preserved, and that it can be used in multiple rounds of bellwether trials since the experts cannot be expected to be available in perpetuity, or for multiple trials (potentially across the country), in light of the age of this litigation and two postponements of trials this year.

5. **Deposition Designations for Bellwether Trials.**

The Parties and the Court were close to finalizing all deposition designations for the TPP trial. Plaintiffs have already begun to update those designations for use at any upcoming trial that would include general causation (for example, the designations of ZHP 30(b)(6) witness Min Li, as ruled on by the Court, have been supplemented with general causation testimony and have been provided to counsel for ZHP). The Court should order the Parties to meet and confer on those updated

designations and then schedule prompt oral arguments on the remaining issues so that the current momentum can be utilized to finalize these designations expeditiously.

6. **Witness and Exhibit Lists for Bellwether Trials.**

Plaintiffs propose utilizing the witness and exhibit lists already prepared for trial, subject only to modifications due to the substitution of personal injury trials for the economic loss trial. The timing of the exchange should be at least 90 days prior to trial.

7. **Proposed Jury Instructions.**

Plaintiffs proposed filing proposed jury instructions 7 days before any bellwether trial.

8. **ZHP's Intent to Call Maggie Kong or Jinsheng Lin at Bellwether Trials.**

ZHP has informed Plaintiffs that it intends to call Maggie Kong and Jinsheng Lin at any upcoming trial. Thus, Plaintiffs ask the Court to rule on the fully briefed and argued motion to preclude the presentation of both witnesses at any trial in this MDL.

9. **Outstanding Disputes Regarding Reports or Discovery of Causation Experts.**

Plaintiffs are unaware of any outstanding disputes. Defendants have indicated that they will be requesting that the Court repeat the Daubert process for the general

causation experts, due to the amendments to Rule 702. As Judge Kugler properly applied the standard, as gatekeeper, there is no good reason to go back over that ground which was thoroughly covered by the Court already. That would be nothing more than a distraction, and instrument of delay.

Similarly, Defendants have indicated that they will be offering to conduct a science day for the Court on general causation. At this point in the litigation, long after the Daubert process for the general causation experts, with the litigation nearly reaching trial twice this year, this is unnecessary, and will distract the parties and the Court from the substantive work that must be done.

10. Unresolved *Daubert* Issues.

On March 18, 2022, Defendants filed a motion for clarification regarding the permissible scope of Plaintiffs' experts Dr. Hecht's and Dr. Lagana's general causation opinions for n-nitrosodimethylamine (NDEA). (ECF 1976). In their March 29, 2022 agenda letter, Plaintiffs informed the Court and Defendants that they were preparing their opposition as well as a cross motion for clarification of the Court's ruling on another Plaintiff expert, Dr. Panigrahy, which Plaintiffs believe mistakenly limited his testimony on NDEA causation to pancreatic cancer. (ECF 1983). At the related case management conference on March 30, 2022, the Court suggested "the

two sides just talk to each other" before proceeding further with the motions, and the motions were tabled. (3/30/2022 Hearing Tr. 19:1-2).

During the subsequent meet and confer, Plaintiffs proposed including the motions as part of the first set of relevant trial motions. Defendants explained that they intend to file omnibus Rule 56 motions for summary judgment on personal injury claims related to NDEA and cancers other than pancreatic, and thus wanted to have the clarification motions decided before any Rule 56 motions on the personal injury cases based on the underlying *Daubert* decisions. Plaintiffs agreed that if the Court is inclined to allow the filing of such a motion (Plaintiffs object to the filing of Rule 56 motions directed to specific personal injury cases before the cases are fully worked up for trial, including specific causation experts), the Plaintiffs would agree to hold these motions, to be heard prior to the filing of dispositive motions. (ECF 2026). The Court agreed with the Parties, and the motions have been held in abeyance ever since. (4/29/2022 Hearing Tr. 13:16-14:8).

Before any bellwether trial that implicates NDEA, the Parties will need to complete the briefing on these issues and receive a decision from the Court.

11. Need to Supplement Plaintiff Fact Sheets.

Plaintiffs agree that the PFSs should be updated on a rolling basis in the ordinary course, for example to include any recent treatment and medical records, information regarding the intervening death of a plaintiff, and other issues.

12. Schedule for Completion of Punitive Damages Discovery.

Plaintiffs have sent ZHP, Teva, and Torrent a proposed stipulation for the purposes of punitive damages. Plaintiffs await Defendants' response, and are hopeful that the Parties can reach agreement on this issue.

13. Submission of a Pretrial Order.

The Parties submitted a PTO in March for the TPP trial and were hours away from submitting an updated PTO for the rescheduled TPP trial. As a result of this process, Plaintiffs do not believe a future PTO is necessary or helpful to the Parties. Plaintiffs' counsel have never submitted PTOs in other MDLs. Given the sophistication of the Parties' counsel, the highly developed record and significant pretrial briefing accompanying any trial, and the contentious nature of the MDL precluding agreement on most issues, Plaintiffs ask the Court to either forego the submission of a PTO for any future trial or allow the Parties to submit a streamlined version of a PTO for the Court's approval (for example, dispensing with the need for the parties to list contested issues - while still requiring that the parties stipulate

as to facts and issues that cannot reasonably be disputed). Of course, even without a formal PTO, the Parties would exchange witness and exhibit lists, and submit stipulations as discussed above. The Parties and the Court can discuss this issue as we start to move forward.

14. Consumer Economic Loss Trials

Plaintiffs submit that the economic loss track, which the parties worked so hard on (with two trials adjourned close to starting), should not be pushed aside, as this would be unduly prejudicial to the Parties. As the Court is aware, there is a consumer economic loss track separate but concurrent to the TPP track. The consumer cases will not implicate the issues of concern to the Court with regard to the TPPS. Plaintiffs propose a consumer economic loss subclass trial against ZHP, Teva and Torrent, given the amount of work that has been completed with these three defendants in preparation for the previously set TPP subclass trial. The same claims were certified for the consumer classes as the TPP classes, so the pre-trial MIL rulings in the bellwether TPP subclass trial would largely apply to the claims for a consumer subclass trial, and the additional motions would flow from the work already performed.

For background, the consumer subclasses were certified at the same time as the TPP subclasses on February 8, 2023. At substantial time and expense, direct and

publication class notice was provided to consumers thereafter, now nearly one year ago. All class representatives have been deposed, and merits fact discovery has been completed as to the causes of action alleged and certified. There should not be any additional fact discovery to be completed, but if Defendants argue otherwise, it can be completed quickly. A schedule can be set for consumer damages expert reports, and related expert depositions, summary judgement motions and trial to proceed in short order.

It should be noted that the anticipated merits expert areas would be similar but not identical to those for the bellwether TPP subclass trial. Further, in conjunction with merits expert reports for a consumer class trial against ZHP, Teva, and Torrent, and in an effort to address certain questions raised by the Court in the context of the TPP trial, Plaintiffs intend to present an expert report(s) as to consumer damages using a conjoint or similar analysis, based on a market research assessment that uses statistical analysis and surveys to determine the value consumers of the at-issue valsartan products place on the attributes of that product, taking into account both the presence of nitrosamines in the product as well as its therapeutic value. [1]

[1] As repeatedly recognized by Judge Kugler, no reasonable consumer would purchase the at-issue nitrosamine-laden valsartan, even if they were able to choose a contaminated drug in the first place (which they could not). *See* ECF 728 at 11 ("Plaintiffs' alleged economic injury is that they did not receive the benefit of their bargain when they purchased Defendants' VCDs because they were contrary to

Plaintiffs also intend to present an expert report which will provide calculations and analysis of available sales data (quantity and pricing) as to the at-issue valsartan sold by the trial defendants. Plaintiffs anticipate that all lingering fact discovery (if any), expert reports, expert depositions, and summary judgment briefing can be completed in a matter of months once the Court indicates this track will be pursued.

Defendants' warranties and representations—that is, the VCDs were adulterated, misbranded, non cGMP compliant, unlawful to sell, and therefore essentially worthless"); ECF 775 at 19-20 ("This Court finds that contaminated drugs are economically worthless at the point of sale by virtue of the dangerousness caused by their contamination, regardless whether the sold VCDs actually achieved the medical purpose of lowering blood pressure. Put differently, contaminated drugs, even if medically efficacious for their purpose, cannot create a benefit of the bargain because the contaminants, and their dangerous effects, were never bargained for. Further, contaminated drugs do create a present injury because their sale should never have occurred."); ECF 2261 at 88 ("The Court has considered carefully all of the parties' arguments and concludes that Dr. Conti has set forth a general calculus, i.e. mathematical model, which, although possibly flawed because the data are not available or forthcoming, may reliably support her presumption of the worthlessness of the sold VCDs."); ECF 2657 at 7; ECF 2694 ("Ds have repeatedly sought the Court to repudiate Ps worthlessness theory: at the motion to dismiss stage, at the class certification stage, and recently in a motion to decertify the certified classes... Regardless of what this argument is called...these theories hinge on different legal perspectives and on genuinely disputed, material facts for the trial fact-finder. Pursuant to Rule 56(a), the parties' arguments dispute a material fact about the amount of damages—from none to the full amount TPPs reimbursed for the insureds' scripts."); *see also* ECF 2469 at 13 (Special Master stating: " Plaintiffs point out that the Court has already determined that the VCDs contaminated with carcinogenic substances are economically worthless, 'regardless whether the sold VCDs actually achieved the medical purpose of lowering blood pressure.'").

Additionally, Plaintiffs will be seeking leave to re-open the expert record for the bellwether TPP subclass trial - if necessary to address the Court's concerns raised before the second scheduled start of that trial. Prior to this, Plaintiffs proceeded in accordance with the law of the case that their claims, damages theory, and Dr. Conti's economic model and opinions all were to be put before a jury. [2] If additional areas that were not previously an issue now need to be addressed, in fairness Plaintiffs should be provided an opportunity to supplement the TPP subclass trial record. This likely can be accomplished at the same time, and in tandem, with the work-up of a consumer economic loss subclass trial against ZHP, Teva, and Torrent.[3]

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[2] In *Zantac* , raised by this Court at the October 10, 2024 conference, the Eleventh Circuit already has ruled in the context of standing that TPPs may pursue a worthlessness theory for contaminated, adulterated, or non-cGMP compliant drugs. *See In re Zantac (Ranitidine) Prods. Liab. Litig.* , No. 21-10335, 2022 WL 16729170, at *3 (11th Cir. Nov. 7, 2022) (reversing dismissal of TPP claims for purported lack of Article III standing where TPP alleged "that [it] provide[d] eligible members with health and welfare benefits, including the payment of and reimbursement for prescription drugs" and had reimbursed members for purchasing worthless Ranitidine Products; economic injury sufficient where TPP alleges "payments or reimbursements for a product that was economically worthless") (internal quotation omitted).

[3] *See supra* fn.1; *see also Am. C.L. Union v. Mukasey* , 534 F.3d 181, 187 (3d Cir. 2008) ("Under the law-of-the-case doctrine, when a court decides upon a rule of law, that decision should continue to govern the same issues in subsequent stages in the same case.") (internal quotation marks omitted).

Respectfully,

Adam M. Slater
Plaintiffs' Liaison Counsel

Cc: Counsel of record (via ECF)

BELLWETHER PERSONAL INJURY PLAINTIFFS

Last Name	First Name	Picked by	Type of Cancer	SFC Named Defendants
Bonmon	Yolanda	Plaintiff	Small Intestine	ZHP, Huahai, Solco, Teva, Actavis, Aurobindo, Mylan, Apothecare Pharmacy III
Briones	Joe	Plaintiff	Colorectal	ZHP, Huahai, Solco, Prinston Aurobindo, Teva, Actavis, Avkare, Bryant Ranch Repack, Cardinal Health, Major Pharmaceuticals, Northwind Pharmaceuticals
Brown	Janice	Defense	Esophageal	Aurobindo Pharma, Ltd., Zhejiang Huahai Pharmaceutical Co., Ltd., AuroLife Pharma, LLC, Aurobindo Pharma USA, Inc., Huahai U.S., Inc., Solco Healthcare US, Ltd., CVS Health, Walgreens, Prinston Pharmaceutical, Inc.
Crawford	Rita	Defense	Small Intestine	ZHP, Huahai, Solco, Prinston, A-S Medications Solutions, HJ Harkins, NuCare Pharmaceuticals, Remedy Repack, ABC, McKesson, CVS, Walgreens
Dawson	Nellie	Defense	Colorectal	ZHP, Huahai, Solco, Prinston, Mylan, Teva, Actavis, Cardinal Health, Humana
Dufrene	Lana	Defense	Kidney	Zhejiang Huahai Pharmaceutical Co Ltd, Prinston Pharmaceutical, Inc., Solco Healthcare US, LLC, Huahai US, Inc., Teva Pharmaceuticals USA, Inc., Torrent Pharmaceuticals, Ltd.
Durl	Welch	Defense	Liver	Aurobindo, Hetero, Mylan, ZHP, Acetris, A-S Medication Solutions, Aurobindo, AvKare, Camber, HJ Jarkins Co., Huahai, NuCare Pharmaceuticals, Preferred Pharmaceuticals, Remedy Repack, CVS Health, Hetero USA, Printson Pharmaceutical
Fields	Tivis	Both	Colorectal	ZHP, Solco, Prinston, Mylan, Rite Aid, Wal-Mart
Ganim	Bambi	Both	Liver	ZHP, Huahai US, Prinston, Solco, Hetero, Camber, Mylan, Torrent, Cigna
Garcia	Robert	Defense	Colorectal	ZHP, Solco, Hauhai, Prinston, Teva, Actavis, Torrent, Cigna, Walgreens, Walmart
Guillory	Maxine	Plaintiff	Colorectal	ZHP, Hauhai, Solco, Prinston, Teva, ABC, Cardinal Health, McKesson, Walgreens, Fred's Pharmacy
Hanna	Nabil	Plaintiff	Stomach	Aurobindo Pharma Ltd., Zhejiang Huahai Pharmaceutical Co., Ltd., Arrow Pharm (Malta) Ltd., Aurolife Pharma, LLC, Aceteris, LLC, A-S Medication Solutions, LLC, Aurobindo Pharma USA, Inc., H J Harkins Co, Inc., Huahai U.S., Inc.NuCare Pharmaceutical, Inc., RemedyRepack, Inc., Solco Healthcare U.S., LLC, Walmart, Prinston Pharmaceutical Inc.

Kennedy	Paulette	Defense	Lymphoma	Zhejiang Huahai Pharmaceutical Co., Ltd., Huahai U.S., Inc., Prinston Pharmaceutical, Inc., Teva Pharmaceuticals USA, Inc., Actavis Pharma, Inc., Actavis, LLC, Mylan, N.V., Mylan Laboratories, Inc., The Kroger Co., Walgreens, Amerisource Bergen
Kinkela	Silvano	Defense	Colorectal	ZHP, Huahai, Solco, Prinston, Teva, Actavis, Optum, UnitedHealth
Lee	Robert	Plaintiff	Colorectal	ZHP, Huahai, Prinston, Teva, Actavis, Walmart
Meeks	Ronald	Defense	Esophageal	ZHP, Teva, Actavis, Huahai, Solco, Prinston
Murawski	Georgia	Plaintiff	Stomach	Zhejiang Huahai Pharmaceutical Co., Ltd., Solco Healthcare US, Ltd., Walgreens, Prinston Pharmaceutical, Inc., Huahai U.S., Inc.
Murga	Crusita	Defense	Colorectal	ZHP, Huahai, Solco, Prinston, Mylan, Teva, Actavis, Avkare, Preferred Pharmaceuticals, Remedy Repack, Hetero, Camber, Cigna, Express Scripts
Ochs	Marvella	Defense	Colorectal	Hetero Drugs, Ltd., Hetero Labs, Ltd., Hetero USA, Inc., Avkare, Inc., Camber Pharmaceuticals, Inc., RemedyRepak, Inc., The Kroger Co., Northwind Pharmceuticals, Wal-Mart, Inc.
Pate	Eugene	Defense	Colorectal	ZHP, Huahai, Solco, Prinston, Teva, Mylan, CVS
Pizzolato	Brad	Plaintiff	Prostate	Mylan, ZHP, Torrent, Huahai, Solco, WalMart, Prinston
Ramirez	Richard	Plaintiff	Stomach	Zhejiang Huahai Pharmaceutical Co., Ltd., Mylan Laboratories Ltd., Mylan N.V., Mylan Pharmaceuticals Inc., Huahai U.S., Inc., Solco Healthcare U.S., LLC, Prinston Pharmaceutical Inc., A-S Medication Solutions, Inc., H J Harkins Co., Inc., Nucare Pharmaceuticals, Inc., RemedyRepack, Inc.
Roberts	Gaston	Plaintiff	Liver	ZHP, Prinston, Solco, North Baldwin Family Pharmacy
Smalls	Evon	Plaintiff	Stomach	Zhejiang Huahai Pharmaceutical Co., Ltd., Huahai U.S., Inc., Solce Healthcare U.S., LLC, WalMart, Prinston Pharmaceutical Inc.
Stephens	James	Plaintiff	Colorectal	ZHP, Hauhai, Solco, Mylan, Publix
Suits	James	Plaintiff	Colorectal	ZHP, Solco, Hauhai, Prinston, Teva, Actavis, Mylan, Avkare, Cardinal Health, HJ Harkins, NuCare Pharmaceuticals, Remedy Repack, ABC, McKesson,
Svebek	Michael	Defense	Colorectal	ZHP, Huahai, Solco, Prinston Mylan, Torrent, Remedy Repack
Weygandt	Robert	Plaintiff	Colorectal	ZHP, Solco, Teva, Actavis, Albertsons